Docket No.

251521US96DIV

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

Michael R JOHNSON

SERIAL NO:

NEW APPLICATION

FILED:

HEREWITH

FOR:

SODIUM CHANNEL BLOCKERS

# **INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97**

COMMISSIONER FOR PATENTS ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant(s) wish to disclose the following information.

## REFERENCES

The applicant(s) wish to make of record the references listed on the attached Form PTO-1449 from prior U.S.
Application Serial No. 10/076,571, filed February 19, 2002. Copies of the listed references are attached, where
required, as are either statements of relevancy or any readily available English translations of pertinent portions of
any non-English language references.

A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

#### RELATED CASES

Attached is a list of applicant's pending application(s) or issued patent(s) which may be related to the present
application. A copy of the patent(s), together with a copy of the claims and drawings of the pending application(s)
is attached along with PTO 1449.
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A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

### **CERTIFICATION**

Each item of information contained in this information disclosure statement was first cited in any communication
from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of
this statement.

□ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

## DEPOSIT ACCOUNT

Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number <u>15-0030</u>. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.

James J. Ke

Registration No. 41,504

Customer Number

22850

Tel. (703) 413-3000 Fax. (703) 413-2220 (OSMMN 05/03)

Form PTO 1449 U.S. DEPARTMENT OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE			ATTY DOCKET NO. 251521US96	SERIAL NO. NEW APPLICATION				
LIST OF	REFE	RENCES CITED BY APPL	ICANT	APPLICANT Michae	el R. JOH	NSON		
				FILING DATE HEREWITH		GROUP		
			-	U.S. PATENT DOCUMENTS				
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE	
	AA	4,177,285	12-04-79	Cragoe, Jr. et al.			<del></del>	
	AB	3,794,734	02-26-74	Cragoe, Jr. et al.	<u> </u>			
-	AC	3,864,401	02-04-75	Schultz et al.				
	AD	3,914,253	10-21-75	Cragoe, Jr. et al.				
	AE	3,929,872	12-30-75	Cragoe, Jr. et al.				
	AF	3,931,239	01-06-76	Cragoe, Jr. et al.				
	AG	3,953,476	04-27-76	Cragoe, Jr. et al.	-			
	AH	3,966,966	06-29-76	Cragoe, Jr. et al.	-			
	ΑI	4,006,180	02-01-77	Cragoe, Jr. et al.				
	AJ	4,012,524	03-15-77	Cragoe, Jr. et al.				
	AK	4,159,279	06-26-79	Smith et al.				
	AL	4,163,781	08-07-79	Cragoe, Jr. et al.	<del>                                     </del>			
	АМ	4,163,794	08-07-79	Cragoe, Jr. et al.	<del>                                     </del>			
			04-18-78	Cragoe, Jr. et al.				
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		OTHER REF	ERENCES (	Including Author, Title, Date, Pertine	nt Pages, e	-tc.)		
	AW			ersy: In Vivo Observations and Therap			ecular Cell, Vol. 8, 149-	
·	AX	Michael R. Knowles et a Pulmonary Disease, Cha	I., <u>Amiloride</u> apter 20, pag	in Cystic Fibrosis: Safety, Pharmacokii le 301-316.	netics, and I	Efficacy in	the Treatment of	
	AY	Louis Simchowitz et al., An Overview of the Structure Activity Relations in the Amiloride Series, Chapter 2, page 9-25.						
	AZ	J.R. Sabater et al., <u>Aerosolization of P2y2-Receptor Agonists Enhances Mucociliary Clearance in Sheep</u> , <i>The American Physiological Society</i> , page 2191-2196.						
Examiner			_		Date Cor	nsidered	-	
*Examiner: In	tial if re	eference is considered, w	hether or not	t citation is in conformance with MPEP	609; Draw li	ne through	citation if not in	

Form PTO 1449 (Modified)		U.S. DEPARTMENT OF PATENT AND TRADEN		251521US96	SERIAL NO.  NEW APPLICATION			
LIST OF	REFE	RENCES CITED BY APPL	_ICANT	APPLICANT Micha	ael R. JOH	NSON		
				FILING DATE HEREWITH		GROUP		
				U.S. PATENT DOCUMENTS				
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE	
	AA	4,025,625	05-24-77	Rooney et al.				
	AB	4,196,292	04-01-80	Woltersdorf, Jr. et al.				
	AC	4,087,526	05-02-78	Cragoe, Jr. et al.				
	AD	4,087,542	05-02-78	Cragoe, Jr. et al.				
	AE	4,092,414	05-30-78	Cragoe, Jr. et al.				
	AF	4,100,294	07-11-78	Cragoe, Jr. et al.				
	AG	4,105,769	08-08-78	Rooney et al.				
	АН	4,140,776	02-20-79	Cragoe, Jr. et al.				
	AI	4,145,551	03-20-79	Cragoe, Jr. et al.	_			
	AJ	4,181,727	01-01-80	Cragoe, Jr. et al.	_			
	AK	4,237,130	12-02-80	Cragoe, Jr. et al.		1		
	AL	4,237,144	12-02-80	Cragoe, Jr. et al.				
	AM	4,277,602	07-07-81	Woltersdorf et al.				
	AN	4,291,050	09-22-81	Woltersdorf, Jr. et al.		1		
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		OTHER REF	FRENCES (	Including Author, Title, Date, Pertin	ent Pages (	etc l		
	AW	<del></del>	al., <u>Amiloride</u>	and Its Analogs as Tools in the Study			ournal of Membrane	
	Edward C. Taylor et al., <u>A Facile Route to "Open Chain" Analogues of DDATHF</u> , <i>Heterocycles</i> , Vol. 28, No. 2, 1989.							
	AY	Paul-Michael Windscheif pages 87-92, January 19	i et al., <u>Subs</u> í 994.	tituted Dipyridlethenes and -ethynes a	and Key Pyric	line Building	g Blocks, Synthesis,	
	AZ	Edward J. Cragoe, Jr., <u>T</u>	he Synthesis	s of Amiloride and Its Analogs, page 2	24-38, Chapte	ır 3.		
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Form PTO 1449 U.S. DEPARTMENT OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE		ATTY DOCKET NO. 251521US96	SERIAL NO. NEW APPLICATION					
LIST OF REFERENCES CITED BY APPLICANT			APPLICANT Michael	R. JOH	NSON			
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EXAMINER	<del></del>			NAME.				
	AA	4,003,927	01-18-77	Woltersdorf, Jr. et al.		CLASS	IF APPROPRIATE	
	AB	4,296,122	10-20-81	Cragoe, Jr. et al.	<u> </u>			
	AC	4,317,822	03-02-82	Woltersdorf, Jr. et al.		+		
	AD	4,362,724		Bock et al.				
	AE	4,401,669	08-30-83		<u> </u>			
	AF	3,974,212	08-10-76		<u> </u>			
	AG	3,984,465	10-05-76	<u> </u>	<u> </u>			
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		3,984,552	10-05-76		<b>-</b>			
	AI	4,067,980	01-10-78					
	AJ	4,085,117	04-18-78					
	AK	4,085,211	04-18-78					
	AL	4,246,406	01-20-81					
AM 3,4		3,472,848	10-14-69	Edward J. Cragoe, Jr. et al.				
	AN	3,544,571	12-01-70	Edward J. Cragoe, Jr., et al.				
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		OTHER REF	ERENCES (I	ncluding Author, Title, Date, Pertinen	nt Pages, e	tc.)		
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	Pallav L. Shah, M.D., <u>Chapter 7. Progress in the Treatment of Pulmonary Disease in Cystic Fibrosis</u> , Annual Repor AX Medicinal Chemistry, Vol. 36, pages 67-76, 2001.							
	Dieter Worlitzsch et al., Effects of Reduced Mucus Oxygen Concentration in Airway Pseudomonas Infections of Cystic Fibrosis Patients, The Journal of Clinical Investigation, February 2002, Volume 109, Number 3, pages 317-336.							
	AZ	Edward J. Cragoe, Jr., et al., <u>Chapter 7: Diuretic Agents</u> , <i>Annual Reports in Medicinal Chemistry</i> , 1966, page 59-68.						
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Form PTO 1449 U.S. DEPARTMENT OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE			COMMERCE MARK OFFICE	ATTY DOCKET NO. 251521US96	SERIAL NO. NEW APPLICATION			
LIST OF	REFE	RENCES CITED BY APPL	.ICANT	APPLICANT Michae	I R. JOHI	NSON		
				FILING DATE HEREWITH		GROUP		
			-	U.S. PATENT DOCUMENTS		<u> </u>		
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE	
-	AA	3,991,106	11-09-76	Cragoe, Jr., et al.				
	AB	3,991,087	11-09-76	Cragoe, Jr. et al.				
	AC	3,989,749	11-02-76	Cragoe, Jr. et al.				
	AD	3,987,091	10-19-76	Cragoe, Jr. et al.				
	ΑE	3,979,361	09-07-76	Schultz et al.				
	AF	3,976,686	08-24-76	Cragoe, Jr. et al.				
	AG	3,976,681	08-24-76	Cragoe, Jr. et al.				
	АН	3,958,004	05-18-76	Cragoe, Jr. et al.				
	ΑI	3,956,374	05-11-76	Shepard et al.			·	
	AJ	3,928,624	12-23-75	Cragoe, Jr. et al.				
	AK	3,894,065	07-08-75	Cragoe, Jr. et al.			<del></del>	
	AL	3,668,241	06-06-72	Cragoe, Jr. et al.	†			
	AM	3,625,950	12-07-71	Edward J. Cragoe, Jr.				
	AN	4,298,743	11-03-81	Cragoe, Jr. et al.				
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		OTHER REFI	ERENCES (I	ncluding Author, Title, Date, Pertiner	ıt Pages, e	tc.)	<u> </u>	
	AW			7: Diuretic Agents, Annual Reports in			965, page 67-77.	
	Robert L. Smith, et al., <u>Chapter 8: Diuretics</u> , <i>Annual Reports in Medicinal Chemistry</i> , Volume 11, pages 71-79, 1976.							
	AY	Robert L. Smith, et al., <u>C</u>	hapter 7: Di	uretics, Annual Reports in Medicinal Ch	emistry, Vo	lume 13, pa	ges 61-70, 1978.	
	AZ	Edward J. Cragoe, Jr., St Laboratories, 1979, page	tructure-Actives 1-20.	vity Relationships in the Amiloride Serie	s, Merck SI	narp and Do	hme Research	
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EXAMINER		DOCUMENT	DATE	NAME		CLASS	SUB		ILING DATE
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-	AA	3,313,813 3,573,306	04/11/67	Cragoe					
	AC	3,373,300	03/30/71	K.L. Shepared et al.					
	AD		-			-			
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		OTHER REI	FERENCES (I	ncluding Author, Title,	, Date, Pertinent	Pages, e	c.)		
	AW	J. B. BICKING, et al., J. HALOPYRAZINECARB	Med. Chem., OXAMIDES",	vol. 8, no. 5, pp. 638-64 1965.	12, "PYRAZINE D	DIURETIC	S. I. N-AMI	DINO-3	3-6-
	R. F. EPAND, et al., British Journal of Cancer, vol. 63, no. 2, pp. 247-251, "REVERSAL OF INTRINSIC MULTIDRUG RESISTANCE IN CHINESE HAMSTER OVARY CELLS BY AMILORIDE ANALOGS", 1991.							ULTIDRUG	
	T. M. COCKS, et al., British Journal of				i, no. 1, pp. 67-76	6, 1988.			
	AZ	T. R. KLEYMAN, et al., American Journal of Physiology, vol. 260, no. 2, Pt. 1, pp. C271-C276, 1991.							
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		OTHER REFER	ENCES (	Including Autho	or, Title, Date, Pe	rtinent Pages, e	tc.)	
	AW	K. E. BARRETT, et al., Ann	ual Rev. I	Physiol. vol. 2000	0, no. 62, pp. 535-	572.		
	R.F. Epand, et al., "REVERSAL OF INTRINSIC MULTIDRUG RESISTANCE IN CHINESE HAMSTER OVARY CE AMILORIDE ANALOGS", Br. J. Cancer (1991), 63, pp. 247-251.							TER OVARY CELLS BY
Kim E. Barrett, et al., "CHLORIDE SECRETION BY THE INTESTINAL EPITHELIUM: MOLECULAR BASIS AN REGULATORY ASPECTS", Annu. Rev. Physiol. 2000, 62, pp. 535-572.						R BASIS AND		
	AZ Copy of Form PCT/IPEA/408, Written Opinion for International Application No. PCT/US03/04817, filed February 19, 2							filed February 19, 2003.
Examiner						Date Co	nsidered	
*Examiner: Ini conformance	itial if re	eference is considered, whetlet considered. Include copy of	her or not f this form	t citation is in cor	nformance with MF	PEP 609; Draw I	ine through	citation if not in